

§ 113.34 Detection of hemagglutinating viruses.

The test for detection of hemagglutinating viruses provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Final container samples of completed product rehydrated as recommended on the label shall be used as inoculum: *Provided*, That poultry vaccines distributed without diluent shall be rehydrated with 30 ml of sterile distilled water per 1,000 doses and used as inoculum. When one or more fractions are to be used in combination with Newcastle Disease Vaccine, test samples shall be collected from bulk suspensions of each prior to mixing with the Newcastle Disease Vaccine.

(b) Each of ten 9- to 10-day-old embryonating eggs from Newcastle disease susceptible flocks shall be inoculated into the allantoic cavity with 0.2 ml of the undiluted inoculum.

(1) Test five uninoculated embryos of the same age and from the same flock as those used for the test as negative controls.

(2) Test an allantoic fluid sample of Newcastle disease virus as a positive control.

(c) Three to five days post-inoculation, a sample of allantoic fluid from each egg shall be tested separately by a rapid plate test for hemagglutinating activity using a 0.5 percent suspension of fresh chicken red blood cells.

(d) If the results are inconclusive, one or two blind passages shall be made using fluids from each of the original test eggs. Fluids from dead and live embryos may be pooled separately for inoculum in these passages.

(e) If hemagglutinating activity attributable to the product is observed, the serial is unsatisfactory.

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§ 113.35 Detection of viricidal activity.

The test for detection of viricidal activity provided in this section shall be conducted when such a test is prescribed in an applicable standard requirement or in the filed Outline of Production for each inactivated liquid

biological product used as diluent for a desiccated live virus vaccine in a combination package.

(a) Bulk or final container samples of completed product from each serial shall be tested.

(b) The product shall be tested with each virus fraction for which it is to be used as a diluent. If the vaccine to be rehydrated contains more than one virus fraction, the test shall be conducted with each fraction after neutralization of the other fraction(s), and/or dilution of the vaccine beyond the titer range of the other fraction(s), or the test shall be conducted using representative single-fraction desiccated vaccines which are prepared by the licensee and which are licensed. *Provided*, That the Administrator may authorize licensees to prepare and use unlicensed single-fraction vaccines for this purpose.

(c) Test procedure: (1) Rehydrate at least two vials of the vaccine with the liquid product under test according to label recommendations and pool the contents.

(2) Rehydrate at least two vials of the vaccine with the same volume of sterile purified water and pool the contents.

(3) Neutralize to remove other fractions, if necessary.

(4) Hold the two pools of vaccine at room temperature (20 ° to 25 °C) for 2 hours. The holding period shall begin when rehydration is completed.

(5) Titrate the virus(es) in each pool of vaccine as provided in the filed Outline of Production or an applicable standard requirement.

(6) Compare respective titers.

(d) If the titer of the vaccine virus(es) rehydrated with the product under test is more than 0.7 log₁₀ below the titer of the vaccine virus(es) rehydrated with sterile purified water, the product is unsatisfactory for use as diluent.

(e) If the product is unsatisfactory in the first test, one retest to rule out faulty techniques may be conducted using four vials of the vaccine for each pool and the acceptability of the product judged by the results of the second test.

(f) Liquid products found to be unsatisfactory for use as diluent by this test